K081076

JUN 20 2008

Pre-Market Notification 510(k) Summary

1. Sponsor Information:

Company Name & Address:	Velocity Medical Solutions, LLC 75 Fifth Street, Suite 221, Atlanta, GA 30309
Contact Person:	Timothy Fox, Ph.D.
Contact Title:	President
Contact Phone Number:	404-272-9217
Contact Fax Number:	404-873-8326
Date of Summary:	April 4, 2008

2. Device Name and Classification:

Common and Usual Name:	Picture Archiving and Communication System (Medical Imaging Software)
Proprietary Name:	VelocityAIS or VelocityAI
Classification Name:	Image Processing System, Radiology (21 CFR § 892.2050)
Performance Standards:	No applicable performance standards have been issued under section 514 or under section 513(b) of the Food, Drug and Cosmetic Act.

3. Predicate Device(s):

Velocity Medical Solutions, VelocityAIS (K070248)
GE Medical Systems, Advantage Windows CT/PET Fusion (K010336)
GE Medical Systems, Volume Viewer Plus (K041521)
MIMvista Corp., MIMVista (K071964)

4. Description of Device:

Version 2.0 of VelocityAIS, also marketed as VelocityAI with this version, is a stand-alone software product that provides medical image processing designed to facilitate the oncology or other clinical specialty work flow by allowing the comparison of medical imaging data from different modalities, points in time, and/or scanning protocols. The product provides users with the means to display, co-register and fuse medical images from multiple modalities including PET, SPECT, CT, and MR, draw Regions of Interest (ROI), calculate, and report relative differences in pixel intensities, Standardized Uptake Value (SUV) or other

values within those regions, and import and export results to and from commercially available radiation treatment planning systems and PACS devices.

Version 2.0 of the product contains the additional features of:

- Automated deformable registration
- Anatomical atlas based segmentation tools
- Operating systems compatibility with MicroSoft Windows XP Home and Professional (Service Pack 2), MicroSoft Vista Home and Professional, Linux (CentOS) and MacOSX (Leopard).

VelocityAIS (VelocityAI) is used as a stand-alone application on recommended Off-The-Shelf (OTS) computers supplied by the company or by the end-user.

5. Indications for Use:

VelocityAIS (VelocityAI) is a stand-alone software product that provides the physician a means for comparison of medical imaging data from multiple DICOM conformant imaging modality sources. It allows the display, annotating, volume rendering, registration and fusing of medical images as an aid during use by diagnostic radiology, oncology, radiation therapy planning and other medical specialties. VelocityAIS (VelocityAI) is not intended for mammography diagnosis.

6. Comparison with Predicate Device(s):

The VelocityAIS (VelocityAI) software is substantially equivalent to the predicate devices identified. It is similar in characteristics, materials, features, has similar technological features, intended use and indications for use as the predicates, and does not pose any new issues of safety and effectiveness.

7. Non-Clinical Performance Summary:

Velocity Medical Solutions has verified and validated that the VelocityAIS (VelocityAI) software meets its functional specifications and performance requirements.

8. Conclusions:

In summary, Velocity Medical Solutions, LLC, is of the opinion that the modified VelocityAIS (VelocityAI) does not introduce any new potential safety risks, is as effective, and performs as well as devices currently on the market, and concludes that the product is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 20 2008

Velocity Medical Solutions, LLC
% Mr. Paul Sumner
Vice President of Regulatory Quality & Clinical Systems
Arkin Consulting Group, LLC
1733 Canton Lane
MARIETTA GA 30062

Re: K081076
Trade/Device Name: VelocityAIS (also "VelocityAI")
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 21, 2008
Received: May 23, 2008

Dear Mr. Sumner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): ~~K070248~~ K081076

Device Name: VelocityAIS (also "VelocityAI")

Indications For Use:

VelocityAIS (VelocityAI) is a stand-alone software product that provides the physician a means for comparison of medical imaging data from multiple DICOM conformant imaging modality sources. It allows the display, annotating, volume rendering, registration and fusing of medical images as an aid during use by diagnostic radiology, oncology, radiation therapy planning and other medical specialties. VelocityAIS (VelocityAI) is not intended for mammography diagnosis.

Prescription Use XX AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K081076